



OLIVER B. MITCHELL III
PO BOX 1705
LONG BEACH, CALIFORNIA 90801
PH: (562) 719-3872
FAX: (888) 829-7124
REDPATCHMARINE@HOTMAIL.COM
IN PRO PER

LACV1903608-PSG-JPRx
UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT COURT OF CALIFORNIA

OLIVER B. MITCHELL III,
Plaintiff,

vs.

LYDIE L. HAZAN, M.D.; and AXIS
CLINICAL TRIALS
Defendant.

CASE NUMBER _____

COMPLAINT FOR INJUNCTIVE RELIEF

COMPLAINT FOR INJUNCTIVE RELIEF

INTRODUCTION

1. This is an action under the Freedom of Information Act ("FOIA") seeking the release of clinical records relating to the Plaintiff participation in a clinical study and challenging Dr. Hazan's policy to withhold documents otherwise subject to a Freedom of Information Act request for reasons outside the statutory exemptions.

2. Plaintiff, Oliver B. Mitchell III, sought access to records related to his participation in Axis Clinical Trials syphilis study, in or around the year 2016. This case concerns documents that Mr. Mitchell identified as responsive but Axis Clinical Trials failed to disclose. Instead, Dr. Hazan and Axis Clinical Trials failed to acknowledge the request prompting litigation. Because this justification for denial does not fall within one of the statutorily designated exemptions to the FOIA, Defendants improperly withheld clinical records from Mr. Mitchell.

3. Clinical Trials are "experiments" or observations done in clinical research. Such

1 prospective “biomedical” or “behavioral” research studies on human participants are designed to
2 answer specific questions about biomedical or behavioral interventions. Axis Clinical Trials
3 specializes in Hepatitis C, Women’s Health, Pediatrics, Vaccines, Rheumatology and Dermatology
4 just to name a few.

5 4. On Monday, November 6, 2017, Mr. Mitchell first began to request documents under
6 the FOIA from Defendants Lydie L. Hazan and Axis Clinical Trials. To date, the Plaintiff has
7 received no response to his request.

8 5. The Plaintiff is legally entitled to these documents, which were requested over a year
9 and a half ago. Axis Clinical Trials has far exceeded the statutory and regulatory time limitation to
10 respond to the Plaintiffs request.

11 6. Given the seriousness of the violations at hand, it is of concern that the requested
12 documents are disclosed to the Plaintiff. Accordingly, this Court should order Defendants to provide
13 the requested records to Mr. Mitchell immediately.

14 JURISDICTION & VENUE

15 7. This Court has subject matter jurisdiction over this action and personal jurisdiction
16 over the parties pursuant to 5 U.S.C. § 552(a)(4)(B) and 5 U.S.C. § 552(a)(4)(A)(vii). This Court also
17 has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. §§ 701–706.

18 8. Because Defendant failed to comply with the requirements to respond set forth in 5
19 U.S.C. § 552(a)(6)(A), Plaintiffs have constructively exhausted their administrative remedies and are
20 entitled to proceed with this judicial action pursuant to 5 U.S.C. § 552(a)(6)(C)(i).

21 9. Venue is proper in this district under 5 U.S.C. § 552(a)(4)(B) because Defendants
22 principal place of business is in California.

23 PARTIES

24 10. Plaintiff, Oliver B. Mitchell III, is a resident of Los Angeles, California.

25 11. Defendant, Lydie L. Hazan, is a medical doctor and founder and Chief Executive
26 Officer for Axis Clinical Trials.
27
28

12. Defendant, Axis Clinical Trials, is a large clinical center that boasts some of the top experts in California who specialize in Hepatitis C, Women's Health, Pediatrics, Vaccines, Rheumatology, and Dermatology. Axis Clinical Trials employs experts are professors at UCLA, and physicians at Cedars Sinai Medical Center, Olympia Medical Center, and City of Hope. They are scientists with a large scope of expertise and experience in clinical trials.

STATEMENT OF FACTS

13. As the United States Supreme Court has recognized, "the basic purpose of the FOIA is to open agency action to the light of public scrutiny." Department of Air Force v. Rose, 425 U.S. 352, 372 (1976).

14. On November 6, 2017, the Plaintiff filed a FOIA request with Axis Clinical Trials seeking records relating to his participation in their Syphilis study. Per the FOIA request "Dear, Dr. Hazan, Attached within the body of this email is a request for medical/research records. Attached as a document is a copy of the unsigned Freedom of Information Request (FOIA). Within a few days you should receive a signed copy of the original notice. Thank you, Oliver Mitchell." **EXHIBIT 1**

15. On April 10, 2018, the Plaintiff filed a FOIA request with Axis Clinical Trials seeking records relating to his participation in their Syphilis study. Per the FOIA request "Under the California Public Records Act 6250 et seq., I am requesting copies of all records pertaining to my participation in the Axis Clinical Trials Syphilis blood draw." **EXHIBIT 2**

16. On March 25, 2019, the Plaintiff filed a FOIA request with Axis Clinical Trials seeking records relating to his participation in their Syphilis study. Per the FOIA request "On more than one occasion the following request has been submitted to your office. Please be advised that failure to respond as required by both state and federal statute will result in the immediate commencement of legal action... The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. In so doing, the IRB shall ensure adherence to the criteria for IRB approval as listed in 45 CFR 46.111 and

21 CFR 56.111... While Axis Clinical Trials may not operate medical facilities, through its “donor centers” Axis Clinical Trials “compiles, records, and stores” donor’s medical information... Medical records are legal documents that can be used as evidence via a subpoena duces tecum, and are thus subject to the laws of the country/state in which they are produced. As such, there is great variability in rules governing production, ownership, accessibility, and destruction. In the United States, the data contained within the medical record belongs to the patient, whereas the physical form the data takes belongs to the entity responsible for maintaining the record per the Health Insurance Portability and Accountability Act. Therefore, in accordance with the 21st Century Cures Act, the California Public Records Act 6250 et seq., and the Health Insurance Portability and Accountability Act (HIPPA), 45 C.F.R. Parts 160 and 164, and in accordance with all rules, laws and regulations of the U.S. Department of Health & Human Services, I am requesting copies of “any and all records pertaining to my donations” at Axis Clinical Trials located at 5800 Wilshire Blvd Los Angeles, CA 90036.”

EXHIBIT 3

17. On April 8, 2019, the Plaintiff phoned Dr. Lydie L. Hazan to discuss the Plaintiffs FOIA. Shortly after their conversation, the Plaintiff emailed Dr. Hazan saying “Dear Dr. Hazan, I appreciate your time and assistance regarding this matter. Per our conversation this afternoon at approximately 2 pm, you indicated the following: 1) You indicated that your staff was incorrect in providing me with information regarding my request for records. 2) You indicated that you personally receive and respond to all request for records and documentation. 3) You indicated that you do not maintain copies of any records once a study is complete. 4) You indicated that prior to our conversation today you have not received any other request and/or communication. 5) You indicated that if I wanted study results I should contact your downtown clinic and schedule an appointment for a study. As previously indicated in my letter to you dated March 29, 2019, the records sought required a written response in accordance with both state and federal law. Before you abruptly interrupted me you indicated that "once it's done it done." The attached email is a forwarded email to you dated November 6, 2017. The email attached is in response to a study done at your headquarters

1 clinic on or around April 2016. Since April 2016, I have had in person contact with Axis Clinical
 2 Trials staff who has informed me that the study, results and records in question was a co-op study
 3 between Axis and the Salvation Army. Since you deny "any" communication from me I have
 4 attached the previous communication for your records. Additionally, subsequent letters were sent out
 5 via USPS Certified Mail and USPS First Class Mail indicating delivery and receipt. In accordance
 6 with correspondence sent to you on March 29, 2019, legal action shall commence against you for
 7 failure to adhere to both state and federal law. In the event you indicate that you fail to receive this
 8 email, I have faxed this email and correspondence to the fax numbers as listed on Axis Today. Again,
 9 I thank you for your time and attention to this matter." **EXHIBIT 4**

10 18. On April 8, 2019, the Plaintiff faxed Defendants Lydie Hazan and Axis Clinical Trials
 11 a summary recapping their previous conversation.

12 19. On April 8, 2019, the Plaintiffs fax provider provided receipt that the Plaintiffs fax
 13 was successful in transmission. **EXHIBIT 5**

14 CAUSES OF ACTION

15 20. The Plaintiff repeats and realleges paragraphs 1 -19.

16 21. Defendants failure to timely respond to the Plaintiffs request violates the FOIA, 5
 17 U.S.C. § 552(a)(6)(A)(ii), and the California Public Records Act 6250 et seq.

18 22. Defendants' failure to make a reasonable effort to search for records responsive to the
 19 Plaintiffs request violates the FOIA, 5 U.S.C. § 552(a)(3)(C), and the California Public Records Act
 20 6250 et seq.

21 23. Defendants' wrongful withholding of non-exempt responsive materials violates the
 22 FOIA, 5 U.S.C. § 552(a)(3)(A).

23 PRAYER FOR RELIEF

24 WHEREFORE, Plaintiff respectfully request that this Court enter a judgment for Plaintiff and
 25 award the following relief:

26 a. Order Defendant, by a date certain, to conduct a search that is reasonably likely to lead
 27
 28

1 to the discovery of any and all records responsive to Plaintiffs' November 6, April 10 and March 29,
2 2019 Requests;

3 b. Order Defendant, by a date certain, to demonstrate that it has conducted an adequate
4 search;

5 c. Order Defendant, by a date certain, to produce to Plaintiffs any and all nonexempt
6 records or portions of records responsive to Plaintiffs' November 6, April 10 and March 29, 2019
7 Requests, as well as a Vaughn index of any records or portions of records withheld due to a claim of
8 exemption;

9 d. Enjoin Defendant from withholding the requested records;

10 e. Enjoin Defendants from charging Plaintiff fees for the processing of their request;

11 f. Award Plaintiff its costs and attorney's fees reasonably incurred in this action,
12 pursuant to 5 U.S.C. § 552(a)(4)(E); and
13

14 g. Grant Plaintiffs such other and further relief as the Court may deem just and proper.
15

16 Respectfully submitted this 29th day of April 2019.
17
18

19 

20 Oliver B. Mitchell III (Pro Se)

21 PO Box 1705

22 Long Beach, CA

23 90801

24 Tel: (562) 719-3872

25 Fax: (888) 829-7124

26 redpatchmarine@hotmail.com
27
28

OLIVER B. MITCHELL III

VS

**LYDIE L. HAZAN, M.D.; and AXIS
CLINICAL TRIALS**

EXHIBITS

1 - 5

Oliver Bruce Mitchell III
622 Wall Street
Los Angeles, California
90014

November 6, 2017

AXIS CLINICAL TRIALS
5800 Wilshire Blvd
Los Angeles, CA
90036
Office: 310.289.8242
Fax: 310.289.8248
Email: drhazan@axistoday.com

Subj: FREEDOM OF INFORMATION REQUEST

Dear Dr. Hazan,

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use.

Axis Clinical Trials specializes in Hepatitis C, Women's Health, Pediatrics, Vaccines, Rheumatology and Dermatology just to name a few.

Clinical research ethics are the set of relevant ethics considered in the conduct of a clinical trial in the field of clinical research. It borrows from the broader fields of research ethics and medical ethics.

Return of results is a concept in research ethics which describes the extent of the duty of a researcher to reveal and explain the results of research to a research participant. Return of results is particularly discussed in the field of biobanks, where a typical case would be that many members of a community donate biobank specimens for medical research.

In the course of the research, especially in human genomics research, scientists may discover personal health information which could influence the behavior of specimen donors if they had this information.

Under the California Public Records Act 6250 et seq., I am requesting copies of all records pertaining to my participation in the Axis Clinical Trials Syphilis blood draw.

If there are any fees for searching or copying these records, please inform me of the cost if it will exceed \$5.00. However, I would also like to request a waiver of all fees in that the disclosure of the requested information is in the public interest and will contribute significantly to my understanding of your clinical trial. This information is not being sought for commercial purposes.

In responding please provide the following:

1. Copies of all health and billing records.
2. Copies of all records and notes within the patients' medical/research file.

Per your website, Axis Clinical Trials has its own separate Regulatory Department with a turnaround of 24 hours for all documents.

The California Public Records Act requires a response within ten business days. If access to the records I am requesting will take longer, please contact me with a written explanation about when I might expect copies of the requested records.

If you deny any or all of this request, please cite each specific exemption you feel justifies the refusal to release the information and notify me of the appeal procedures available to me under the law.

In order to access the appropriate files the patients name and last four are provided: Oliver B. Mitchell III 3512.

Thank you for considering my request.

Sincerely,



Oliver B. Mitchell III



NEEDS...STILL...BY...MEDICAL...EVA...8242

"GET FREE TREATMENT AND GET PAID TO STAY HEALTHY"

AXIS CLINICAL TRIALS – HEADQUARTERS

5800 Wilshire Blvd., Los Angeles, CA 90036 -- Call EVA (310) 289-8242

1. ACNE – MODERATE TO SEVERE: MEN 18-35 YEARS OF AGE Pays \$300
2. ACNE – MODERATE ; MEN AND WOMEN 12-40 Pays \$150
3. ACTINIC KERATOSIS/SUNSPOTS Pays \$550
4. ECZEMA/ATOPIC DERMATITIS Pays \$570
5. DIABETES + HEART DISEASE Pays \$525
6. OSTEOARTHRITIS – KNEE Pays \$900
7. OSTEOARTHRITIS – KNEE Pays \$900
8. BACTERIAL VAGINOSIS Pays \$675
9. SYPHILIS BLOOD DRAW Pays \$20
- 10.FAMILY PACT (FAMILY PLANNING) FREE FREE FREE

AXIS CLINICAL TRIALS – DOWNTOWN

1636 Wilshire Blvd. 2nd Floor, Los Angeles, CA 90017 -- (213) 484-0180

1. HOT FLASHES: POST MENOPAUSE 40-65 Pays \$525
2. SYPHILIS BLOOD DRAW Pays \$20
3. BACTERIAL VAGINOSIS Pays \$675
4. ACNE – MODERATE ; MEN AND WOMEN 12-40 Pays \$150
5. PEDIATRIC CONSTIPATION/IRRATABLE BOWEL SYNDROME 6-17 Pays \$150
6. FAMILY PACT (FAMILY PLANNING) FREE FREE FREE
- 7.POWERPLAY (WEIGHT MANAGEMENT PROGRAM 4 KIDS)

GET PAID TO STAY HEALTHY

CALL EVA 310 289 8242 or 282 I will help you

FREEDOM OF INFORMATION REQUEST

B M

Mon 11/6/2017 4:59 PM

To: drhazan@axistoday.com <drhazan@axistoday.com>

Cc: Bruce Mitchell <redpatchmarine@hotmail.com>

 1 attachments (19 KB)

AXIS CLINICAL TRIALS FOIA REQUEST.docx;

Dear, Dr. Hazan,

Attached within the body of this email is a request for medical/research records. Attached as a document is a copy of the unsigned Freedom of Information Request (FOIA). Within a few days you should receive a signed copy of the original notice.

Thank you,

Oliver Mitchell

**Oliver Bruce Mitchell III
622 Wall Street
Los Angeles, California
90014**

November 6, 2017

**AXIS CLINICAL TRIALS
5800 Wilshire Blvd
Los Angeles, CA
90036
Office: 310.289.8242
Fax: 310.289.8248
Email: drhazan@axistoday.com**

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Dear Dr. Hazan,

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use.

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Under the California Public Records Act 6250 et seq., I am requesting copies of all records pertaining to my participation in the Axis Clinical Trials Syphilis blood draw.

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In order to access the appropriate files the patients name and last four are provided: Oliver B. Mitchell III 3512.

Thank you for considering my request.

Sincerely,

-----OBM-----

Oliver B. Mitchell III

**Oliver Bruce Mitchell III
PO Box 20560
Long Beach, California
90801**

April 10, 2018

AXIS CLINICAL TRIALS

5800 Wilshire Blvd

Los Angeles, CA

90036

Office: 310.289.8242

Fax: 310.289.8248

Email: drhazan@axistoday.com

U.S. Certified Mail Receipt No. 7017 2680 0000 3773 4247

Subj: FREEDOM OF INFORMATION REQUEST

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Sincerely,



Oliver B. Mitchell III

7017 2680 0000 3773 4247

U.S. Postal Service™ CERTIFIED MAIL® RECEIPT Domestic Mail Only	
For delivery information, visit our website at www.usps.com ®.	
LOS ANGELES, CA 90036	
Certified Mail Fee	\$3.45
Extra Services & Fees (check box, add fee as appropriate)	\$2.75
<input type="checkbox"/> Return Receipt (hardcopy)	\$0.00
<input type="checkbox"/> Return Receipt (electronic)	\$0.00
<input type="checkbox"/> Certified Mail Restricted Delivery	\$0.00
<input type="checkbox"/> Adult Signature Required	\$0.00
<input type="checkbox"/> Adult Signature Restricted Delivery	\$0.00
Postage	\$0.50
Total Postage and Fees	\$6.70
	
Sent To AXIS CLINICAL TRIALS Street and Apt. No., or PO Box No. 5800 WILSHIRE BLVD City, State, ZIP+4® LA, CA 90036	
PS Form 3800, April 2015 PSN 7530-02-000-9047 See Reverse for Instructions	

Fax Message Transmission Result - All Sent

RingCentral <service@ringcentral.com>

Fri 3/29/2019 7:02 PM

To: Oliver Mitchell <redpatchmarine@hotmail.com>

Here are the results of the 3-page fax you sent from your phone number (888) 829-7124:

Name	Phone Number	Date and Time	Result
	+1 (310) 2898248	Friday, March 29, 2019 at 07:00 PM	Sent
	+1 (213) 4131273	Friday, March 29, 2019 at 07:02 PM	Sent

Your fax(es) included the following file(s), which were rendered into fax format for transmission:

File Name	Result
AXIS CLINICAL TRIALS 032919.docx	Success

Oliver Bruce Mitchell III
PO Box 1705
Long Beach, California
90801
PH: (562) 719-3872
FX: (888) 829-7124
redpatchmarine@hotmail.com

March 25, 2019

SENT VIA FAX

AXIS CLINICAL TRIALS
5800 Wilshire Blvd.,
Los Angeles, CA
90036
Office: 310.289.8242
Fax: 310.289.8248
Email: drhazan@axistoday.com

Re: Request for Medical/Research Records

Dear Axis Clinical Trials,

On more than one occasion the following request has been submitted to your office. Please be advised that failure to respond as required by both state and federal statute will result in the immediate commencement of legal action.

Axis Clinical Trials specializes in Hepatitis C, Women's Health, Pediatrics, Vaccines, Rheumatology and Dermatology just to name a few.

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use.

Clinical research ethics are the set of relevant ethics considered in the conduct of a clinical trial in the field of clinical research. It borrows from the broader fields of research ethics and medical ethics.

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. In so doing, the IRB shall ensure adherence to the criteria for IRB approval as listed in 45 CFR 46.111 and 21 CFR 56.111.

Informed consent of human research subjects is obtained in advance of research participation and appropriately documented in accordance with, and to the extent required by federal regulations and IRB policies.

While Axis Clinical Trials may not operate medical facilities, through its "donor centers" Axis Clinical Trials "compiles, records, and stores" donors medical information.

The terms medical record, health record, and medical chart are used somewhat interchangeably to describe the systematic documentation of a single patient's medical history and care across time within one particular health care provider's jurisdiction.

The medical record includes a variety of types of "notes" entered over time by health care professionals, recording observations and administration of drugs and therapies, orders for the administration of drugs and therapies, test results, x-rays, reports, etc. The maintenance of complete and accurate medical records is a requirement of health care providers and is generally enforced as a licensing or certification prerequisite.

Medical records are legal documents that can be used as evidence via a subpoena duces tecum, and are thus subject to the laws of the country/state in which they are produced. As such, there is great variability in rules governing production, ownership, accessibility, and destruction.

In the United States, the data contained within the medical record belongs to the patient, whereas the physical form the data takes belongs to the entity responsible for maintaining the record per the Health Insurance Portability and Accountability Act.

Therefore, in accordance with the 21st Century Cures Act, the California Public Records Act 6250 et seq., and the Health Insurance Portability and Accountability Act (HIPPA), 45 C.F.R. Parts 160 and 164, and in accordance with all rules, laws and regulations of the U.S. Department of Health & Human Services, I am requesting copies of "any and all records pertaining to my donations" at Axis Clinical Trials located at 5800 Wilshire Blvd Los Angeles, CA 90036.

Again, allow me to CLARIFY; that's "any and all records pertaining to my donations."

If there are any fees for searching or copying these records, please inform me of the cost if it will exceed \$5.00. However, I would also like to request a waiver of all fees in that the disclosure of the requested information is in my best interest and will contribute significantly to my understanding of your clinical research. This information is not being sought for commercial purposes.

In responding please provide the following:

1. Copies of all health records and notes within my donor/medical file.
2. Any releaseable information regarding the IRB used in conjunction to my participation at Axis Clinical Trials.

Please be advised at this time, that there are no documents or any other information that is and/or was prepared for Axis Clinical Trials review. In fact, this is simply a request for health information contained within the "donors" files maintained at the donor center.

The California Public Records Act requires a response within ten business days. If access to the records I am requesting will take longer, please contact me with a written explanation about when I might expect copies of the requested records.

If you deny any or all of this request, please cite each specific exemption you feel justifies the refusal to release the information and notify me of the appeal procedures available to me under the law.

In order to access the appropriate files the patients name and last four are provided:

Mitchell, 3512

Please mail, fax and/or email all records to the above address.

Thank you for considering my request.

Sincerely,

3/29/2019

X 

Oliver B. Mitchell III

Signed by: Oliver B. Mitchell III

4/8/2019

Mail - B M - Outlook

Fw: FREEDOM OF INFORMATION REQUEST

B M

Mon 4/8/2019 2:45 PM

To: drhazan@axistoday.com <drhazan@axistoday.com>; redpatchmarine@hotmail.com <redpatchmarine@hotmail.com>

■ 1 attachments (19 KB)

AXIS CLINICAL TRIALS FOIA REQUEST.docx;

Dear Dr. Hazan,

I appreciate your time and assistance regarding this matter.

Per our conversation this afternoon at approximately 2 pm, you indicated the following:

1. You indicated that your staff was incorrect in providing me with information regarding my request for records.
2. You indicated that you personally receive and respond to all request for records and documentation.
3. You indicated that you do not maintain copies of any records once a study is complete.
4. You indicated that prior to our conversation today you have not received any other request and/or communication.
5. You indicated that if I wanted study results I should contact your downtown clinic and schedule an appointment for a study.

As previously indicated in my letter to you dated March 29, 2019, the records sought required a written response in accordance with both state and federal law.

Before you abruptly interrupted me you indicated that "once its done it done."

The attached email is a forwarded email to you dated November 6, 2017. The email attached is in response to a study done at your headquarters clinic on or around April 2016. Since April 2016, I have had in person contact with Axis Clinical Trials staff who has informed me that the study, results and records in question was a co-op study between Axis and the Salvation Army.

Since you deny "any" communication from me I have attached the previous communication for your records. Additionally, subsequent letters were sent out via USPS Certified Mail and USPS First Class Mail indicating delivery and receipt.

In accordance with correspondence sent to you on March 29, 2019, legal action shall commence against you for failure to adhere to both state and federal law.

In the event you indicate that you fail to receive this email, I have faxed this email and correspondence to the fax numbers as listed on Axis Today.

Again, I thank you for your time and attention to this matter.

4/8/2019

Mail - B M - Outlook

Oliver Mitchell

From: B M <redpatchmarine@hotmail.com>
Sent: Monday, November 6, 2017 4:59 PM
To: drhazan@axistoday.com
Cc: Bruce Mitchell
Subject: FREEDOM OF INFORMATION REQUEST

Dear, Dr. Hazan,

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**Oliver Bruce Mitchell III
622 Wall Street
Los Angeles, California
90014**

November 6, 2017

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5800 Wilshire Blvd
Los Angeles, CA
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Office: 310.289.8242
Fax: 310.289.8248
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4/8/2019

Mail - B M - Outlook

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Return of results is a concept in research ethics which describes the extent of the duty of a researcher to reveal and explain the results of research to a research participant. Return of results is particularly discussed in the field of biobanks, where a typical case would be that many members of a community donate biobank specimens for medical research. In the course of the research, especially in human genomics research, scientists may discover personal health information which could influence the behavior of specimen donors if they had this information.

Under the California Public Records Act 6250 et seq., I am requesting copies of all records pertaining to my participation in the Axis Clinical Trials Syphilis blood draw.

If there are any fees for searching or copying these records, please inform me of the cost if it will exceed \$5.00. However, I would also like to request a waiver of all fees in that the disclosure of the requested information is in the public interest and will contribute significantly to my understanding of your clinical trial. This information is not being sought for commercial purposes.

In responding please provide the following:

1. Copies of all health and billing records.
2. Copies of all records and notes within the patients' medical/research file.

Per your website, Axis Clinical Trials has its own separate Regulatory Department with a turnaround of 24 hours for all documents.

The California Public Records Act requires a response within ten business days. If access to the records I am requesting will take longer, please contact me with a written explanation about when I might expect copies of the requested records.

If you deny any or all of this request, please cite each specific exemption you feel justifies the refusal to release the information and notify me of the appeal procedures available to me under the law.

In order to access the appropriate files the patients name and last four are provided: Oliver B. Mitchell III 3512.

Thank you for considering my request.

Sincerely,

4/8/2019

Mail - B M - Outlook

-----OBM-----

Oliver B. Mitchell III